REMARKS

Claims 26 and 28-29 and 34-35 are pending herein. Claims 26, 28-29, and 34-35 are currently rejected as failing to meet the written description requirement. Applicants respectfully traverse this rejection.

As stated in *Capon v. Eshar*, 418 F.3d 1349 (Fed. Cir. 2005):

> The "written description" requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. See *Enzo Biochem,* 296 F.3d at 1330 (the written description requirement "is the quid pro quo of the patent system; the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time"); Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345-46 (Fed.Cir.2000) (the purpose of the written description requirement "is to ensure that the scope of the right to exclude ... does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification"); In re Barker, 559 F.2d 588, 592 n. 4 (CCPA 1977) (the goal of the written description requirement is "to clearly convey the information that an applicant has invented the subject matter which is claimed"). The written description requirement thus satisfies the policy premises of the law, whereby the inventor's technical/scientific advance is added to the body of knowledge, as consideration for the grant of patent exclusivity.

Thus, to determine whether the written description requirement has been met, it is necessary to determine what was already in the art, as well as what Applicants' contribution to the art of oligonucleotide based immunostimulatory compounds actually is. Applicants' contribution to that art was the surprising discovery that replacement of cytosine in a CpG dinucleotide of an immunostimulatory CpG-containing oligonucleotide by 5-hydroxycytosine, 5-hydroxymethylcytosine, N4-alkylcytosine or 4-thiouracil does not diminish, and may enhance the immune stimulatory properties of the oligonucleotide.

Specifically, independent claim 26 recites the use of specified immunostimulatory oligonucleotides to induce an immune response in a patient. The oligonucleotides are limited to those containing an immunostimulatory dinucleotide C*G, wherein C* is defined by the Markush group "selected from the group consisting of 5-hydroxycytosine, 5-hydroxymethylcytosine, N4-alkylcytosine and 4-thiouracil."

In determining whether one skilled in the art would recognize that Applicants were in possession of this invention as of their filing date, the PTO must consider not only Applicants'

disclosure, but also what was known in the art as of Applicants' filing dated. As the court stated in *Capon*,

> The "written description" requirement must be applied in the context of the particular invention and the state of the knowledge. The Board's rule that the nucleotide sequences of the chimeric genes must be fully presented, although the nucleotide sequences of the component DNA are known, is an inappropriate generalization. When the prior art includes the nucleotide information, precedent does not set a *per se* rule that the information must be determined afresh. .... The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.

As in *Capon*, in the present case Applicants' contribution was not that CpG-containing oligonucleotides are immunostimulatory. That was already known, as discussed in detail in Applicants' specification. Nor was Applicants' contribution a particular CpG-containing oligonucleotide sequence as one skilled in the art would consider the vast number of CpG-containing immune stimulatory oligonucleotides already known as of Applicants' filing date. One skilled in the art, however, would recognize Applicants' contribution, that replacement of cytosine in a CpG dinucleotide of any such immunostimulatory CpG-containing oligonucleotide by 5-hydroxycytosine, 5-hydroxymethylcytosine, N4-alkylcytosine or 4-thiouracil would not diminish and may enhance the immunostimulatory activity of any such oligonucleotide.

The rejection cites *Noelle v. Lederman* for the proposition that "A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed." (OA at page 6, emphasis added). Applicants do not dispute this general principle, but respectfully submit that it is inapposite to the present facts. Again, what is known in the art must be considered.

As the court stated in *Capon*,

> It is not necessary that every permutation within a generally operable invention be effective in order for an inventor to obtain a generic claim, provided that the effect is sufficiently demonstrated to characterize a generic invention. See *In re Angstadt,* 537 F.2d 498, 504 (CCPA 1976) ("The examples, both operative and inoperative, are the best guidance this art permits, as far as we can conclude from the record"). While the Board is correct that a generic invention requires adequate support, the sufficiency of the support must be determined in the particular case.

In the present case, one skilled in the art would simply look to the previously existing immunostimulatory oligonucleotides to recognize whether any particular embodiment of the

claimed invention would be operative. If a given CpG-containing oligonucleotide selected from the prior art is immunostimulatory, its sequence will remain immunostimulatory (and perhaps be improved) with Applicants' modification in Applicants' claimed method. If it is not, it will likely continue to not be operative with Applicants' modification in Applicants' claimed method.

In summary, Applicants' respectfully submit that when what was known in the art at the time of Applicants' filing, and Applicants' contribution to the art is also properly considered, it becomes readily apparent that the written description is satisfied in the present case. Accordingly, Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner believes that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned attorney at 781-933-6630.

Respectfully submitted,

Dated: December 4, 2008

By: /Wayne A. Keown/
Wayne A. Keown
Registration No. 33,923

Keown & Zucchero, LLP
500 West Cummings Park
Suite 1200
Woburn, MA 01801
Telephone: 781/938-1805
Facsimile: 781/938-4777